MEDICATION GUIDE

SYMLIN® (SİM-lǐn)
(pramlintide acetate)
injection for subcutaneous use

Read this Medication Guide and Instructions for Use that come with your SYMLIN before you start using it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about SYMLIN?

SYMLIN can cause serious side effects, including:

• severe low blood sugar (hypoglycemia). Even when SYMLIN is carefully added to your mealtime insulin therapy, your blood sugar may drop too low, especially if you have type 1 diabetes. If this severe low blood sugar (hypoglycemia) happens, it is seen within 3 hours after a SYMLIN injection. Symptoms of severe low blood sugar and low blood sugar include:
  o lightheadedness
  o dizziness
  o shakiness
  o sweating
  o hunger
  o fast heartbeat
  o trouble concentrating or confusion
  o change in vision
  o headache
  o irritability
  o drowsiness

People who have severely low blood sugar have had injuries while driving their car, operating heavy machinery or doing other dangerous activities. You and your healthcare provider should talk about a plan to treat low blood sugar. You should have fast-acting sugar (such as hard candy, glucose tablets, juice) or glucagon for injection with you at all times. Call your healthcare provider if you have severe low blood sugar or if you have low blood sugar more often than normal.

You have a higher chance of getting severe low blood sugar if you:

  o do not follow your healthcare provider’s instructions to reduce your insulin use before meals
o use more SYMLIN or insulin than prescribed by your healthcare provider
o change your insulin dose without checking your blood sugar
o eat less food than your usual meal
o are sick and cannot eat
o are more active than usual
o have a low blood sugar level before eating
o drink alcohol

SYMLIN is used with insulin to lower blood sugar, especially high blood sugar that happens after meals.

SYMLIN is taken at mealtimes. The use of SYMLIN does not replace your daily insulin but may lower the amount of insulin you need, especially before meals.

Do not share your SymlinPen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.

What is SYMLIN?

SYMLIN is an injectable prescription medicine used to treat adults with type 1 and type 2 diabetes to control blood sugar. SYMLIN is used when your mealtime insulin dose has not controlled your blood sugar well enough.

It is not known if SYMLIN is safe and effective in children.

Who should not use SYMLIN?

Do not use SYMLIN if you:

• are allergic to SYMLIN or any ingredients in SYMLIN. See the end of this Medication Guide for a complete list of ingredients in SYMLIN.
• cannot tell when your blood sugar is low (hypoglycemia unawareness)
• have a stomach problem called gastroparesis. This is when your stomach does not empty as fast as it should.

What should I tell my healthcare provider before using SYMLIN?

Before you use SYMLIN, tell your healthcare provider about all of your medical conditions, including if you:

• are pregnant or plan to become pregnant. It is not known if SYMLIN will harm your unborn baby. You and your healthcare provider should decide how to best control your blood sugar levels during pregnancy.
• are breastfeeding or plan to breastfeed. It is not known if SYMLIN passes into your breast milk. You and your healthcare provider should decide about the best way to feed your baby if you are using SYMLIN.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SYMLIN slows stomach emptying and can affect medicines that need to pass through the stomach quickly.

How should I use SYMLIN?

• Read the “Instructions for Use” and the Medication Guide and that come with your SYMLIN for information about the right way to use SYMLIN.
• Use SYMLIN exactly as your healthcare provider tells you to use it.
• Your healthcare provider will tell you how much SYMLIN to use and when to use it.
• Your healthcare provider may change your dose if needed.
• If you stop taking SYMLIN for any reason, such as surgery or illness, talk to your healthcare provider about how to re-start SYMLIN.
• To reduce the risk of hypoglycemia, it is important that you plan your meals and physical activity every day while you use SYMLIN. Plan for what you will eat and when you will eat your meals.
• The amount of SYMLIN you use will depend on whether you have type 1 or type 2 diabetes.
• The way you inject SYMLIN is similar to the way you inject insulin. Inject SYMLIN under the skin of your stomach area (abdomen) or upper leg (thigh). Inject SYMLIN at a site that is more than 2 inches away from your insulin injection. Do not inject SYMLIN and insulin in the same site.
• To help reduce the chances of getting a reaction at the injection site, allow SYMLIN to come to room temperature before injecting.
• Use a new needle for each SYMLIN injection. Do not reuse or share your needles with other people. You may give other people a serious infection, or get a serious infection from them.
• Never mix SYMLIN and insulin. Insulin can affect SYMLIN when they are mixed together.
• Do not use SYMLIN if the liquid looks cloudy.
• If you take more than your prescribed dose of SYMLIN, you may get nauseous or vomit, and may not be able to eat the amount of food you usually eat. If you take more SYMLIN than your prescribed dose, pay careful attention to the amount of insulin you use because you may be at more risk for low blood sugar. Contact your healthcare provider for guidance.
• If you miss or forget a dose of SYMLIN, wait until the next meal and take your usual dose of SYMLIN at that meal. **Do not** take more than your usual dose of SYMLIN.

• **Do not share your SymlinPen with other people, even if the needle is changed. You may give other people a serious infection or get a serious infection from them.**

**Using SYMLIN and insulin with type 1 diabetes:**

• When starting SYMLIN, you will need to reduce your dose of mealtime insulin. Your healthcare provider will tell you how to reduce your dose of mealtime insulin the right way.

• You must check your blood sugar as often as your healthcare provider tells you to, which may include before and after every meal and at bedtime.

• The usual starting dose of SYMLIN for people who have type 1 diabetes is 15 micrograms (mcg) injected under your skin.

• Inject SYMLIN under your skin (subcutaneously) just before a major meal. A major meal must have at least 250 calories or 30 grams of carbohydrate.

• If you have not had any nausea for 3 days or more after your dose of SYMLIN is changed, your healthcare provider may tell you to slowly increase your dose of SYMLIN. **Do not** increase your dose of SYMLIN unless your healthcare provider tells you to.

• Tell your healthcare provider right away if you have nausea or low blood sugar after your dose of SYMLIN is changed. Your healthcare provider will tell you what to do.

• Your healthcare provider may make changes to your insulin dose to better control your blood sugar. Your healthcare provider should tell you what the right dose of insulin is for you.

**Using SYMLIN and insulin with type 2 diabetes:**

• When starting SYMLIN, you will need to reduce your dose of mealtime insulin. Your healthcare provider will tell you how to reduce your dose of mealtime insulin the right way.

• You must check your blood sugar as often as your healthcare provider advises you to, which may include before and after every meal and at bedtime.

• The usual starting dose of SYMLIN for people who have type 2 diabetes is 60 micrograms (mcg) injected under your skin.

• Inject SYMLIN under your skin (subcutaneously) just before a major meal. A major meal must have at least 250 calories or 30 grams of carbohydrate.

• If you have not had any nausea for 3 days or more after your dose of SYMLIN is changed, your healthcare provider may tell you to increase your dose of
SYMLIN. Do not increase your dose of SYMLIN unless your healthcare provider tells you to.

- Tell your healthcare provider right away if you have nausea or low blood sugar after your dose of SYMLIN is changed. Your healthcare provider will tell you what to do.
- Your healthcare provider may make changes to your insulin dose to better control your blood sugar. Your healthcare provider should tell you what the right dose of insulin is for you.

What should I avoid while taking SYMLIN?

- See "What is the most important information I should know about SYMLIN?"
- Do not drive, operate machinery, or do other dangerous activities until you know how SYMLIN affects you. Talk to your healthcare provider about the activities you should avoid.
- Alcohol. Drinking alcohol may increase your chances of getting severe low blood sugar.

What are the possible side effects of SYMLIN?

SYMLIN may cause serious side effects, including:

- See "What is the most important information I should know about SYMLIN?"
- injection site reactions. SYMLIN may cause bruising, swelling, or itching at the injection site.

The most common side effects of SYMLIN include:

- nausea
- vomiting
- decreased appetite
- stomach pain
- headache

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of SYMLIN. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
How should I store SYMLIN?

**Unopened SYMLIN:**
- Keep SYMLIN in the refrigerator between 36°F to 46°F (2°C to 8°C), until you are ready to use it.
- Do not freeze. Do not use SYMLIN if it has been frozen.
- Keep unopened SYMLIN out of the light.

**Opened SYMLIN:**
- Keep SYMLIN either in the refrigerator or at room temperature between 36°F to 86°F (2°C to 30°C) for up to 30 days.
- Throw away used SYMLIN after 30 days of use, even if the pen still has medicine in it.
- Do not use SYMLIN (opened or unopened) after the expiration (EXP) date printed on the carton and the label.

Keep SYMLIN and all medicines out of the reach of children.

**General information about the safe and effective use of SYMLIN:**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use SYMLIN for a condition for which it was not prescribed. Do not give SYMLIN to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about SYMLIN. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about SYMLIN that is written for health professionals.

More information, go to www.SYMLIN.com or call 1-800-236-9933.

**What are the ingredients in SYMLIN?**

**Active ingredient:** pramlintide acetate

**Inactive ingredients:** metacresol, D-mannitol, acetic acid, and sodium acetate

This Medication Guide has been approved by the U.S. Food and Drug Administration.
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Distributed by:
AstraZeneca Pharmaceuticals LP
Wilmington, DE 19850

Revised: February 2015